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Published:
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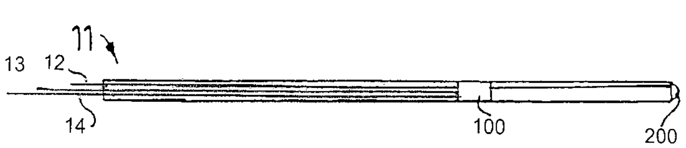
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** FLOW SENSOR AND METHOD FOR MEASURING THE FLOW OF A BODY FLUID



(57) **Abstract:** An implantable flow sensor intended to be implanted into the circulatory system of a human being for sensing the flow of a body fluid comprises a heating element for heating a pyroelectric sensing element of a pyroelectric detector which is adapted to generate a temperature signal representing changes in temperature of its sensing element after interruption of the heating. A flow determining means is provided for determining from the temperature signal data about the body fluid flow rate from cooling of said sensing element after interruption of the heating. The heating element and the sensing element are one and the same, combined heating and sensing element (100). The combined heating and sensing element is piezoelectric, and a voltage source is provided for applying a vibration exciting voltage on the combined heating and sensing element for heating the element. A corresponding method for measuring the flow of the body fluid is described too.

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FLOW SENSOR AND METHOD FOR MEASURING THE FLOW OF A BODY FLUID

Technical Field

The present invention relates to an Implantable flow sensor intended to be implanted into the circulatory system of a human being for sensing the flow of a body fluid, comprising a heating element for heating a pyroelectric sensing element of a pyroelectric detector which is adapted to generate a temperature signal representing changes in temperature of its sensing element after interruption of the heating, and a flow determining means for determining from said temperature signal data about the body fluid flow rate from cooling of said sensing element after interruption of the heating. The invention also relates to a method for measuring the flow of a body fluid in the circulatory system of a human being, wherein a pyroelectric sensing element, intended to be implanted into said circulatory system, is heated by a heating element, whereupon a pyroelectric signal from said sensing element is detected when the temperature changes after interrupted heating for determining the cooling of the sensing element, and data about the body fluid flow rate is determined from the cooling after interrupted heating.

Background

Knowledge of the flow of body fluids in the circulatory system of a human being is without doubt one of the most important parameters for the diagnostic and efficient therapy of the circulatory system. The ability to reliably measure the flow would significantly enhance the diagnostic and therapeutic strength of a circulatory assist device, like a pacemaker.

One established previously known technique for estimating body flows is to measure the cooling of a heated sensor body implanted into the circulatory system. Two different principles of this technique can be distinguished. According to a first one the sensor body is heated to a temperature slightly above, e.g. 1°C above, the temperature of the flowing medium or fluid. This temperature rise of e.g. 1°C is kept constant and the heating power, which then is a measure of the flow, is recorded. This principle allows for a continuous measurement. According to a second principle the sensor is intermittently heated, and after the heating has been switched off, the sensor body cooling speed is recorded. The speed of cooling gives information about the flow.

An example of such a sensor is disclosed in US 5 598 847. The sensor according to this document includes a rigid cylindrical tube, sized to fit within a blood vessel. Inside the tube a heating element and a pyroelectric sensing element are situated. A signal processor is provided for generating a signal indicating the blood flow rate on the basis of the temperature signal received from the sensing element.

A problem in connection with the use of implanted sensing elements resides in the fact that overgrowths, adhering protein layers and clots of blood on the sensing surface impair the sensing ability of the sensing element. Several attempts have been made to solve this problem.

In US 5 344 494 cleaning of the surface of an implant by blasting particulate hard solids towards the surface combined with treatment by ultrasonic vibrations is described.

In WO 99/53972 a specific hard piezoelectric material is proposed for use in an implant, the hardness of this material reducing overgrowth and adherence which would impair sensing properties of the material.

US 6 524 256 discloses a measuring device comprising a catheter which can be positioned in a body cavity, said catheter carrying a sensor for sensing a parameter of interest. A cleaning element in the form of a piezoelectric actuator is coupled to the sensor. When the piezoelectric actuator is set to vibrate, the vibrations are transferred to the sensor for removal of deposits.

The purpose of the present invention is to propose a simple and reliable technique for measuring the flow rate of fluids in the circulatory system of a human being, wherein the problem of ingrowths and overgrowths, adhering protein layers, deposits etc. on an implanted sensing surface is also eliminated.

Disclosure of the Invention

This purpose is obtained by a sensor and a method of the kinds defined in the introductory portion which have the characterizing features of claims 1 and 5 respectively.

The pyroelectric effect is inherent in a very pronounced way in all piezoelectric material. Often this is a disadvantage which has to be compensated for, especially in low frequency applications. In the present invention, on the contrary, the pyroelectric properties of piezoelectric materials are utilized for providing a simple, reliable and quick sensor for determining the flow of a body fluid.

By applying an AC excitation voltage over the piezoelectric element the element is vibrated, and due to losses in the piezoelectric material the element is heated. After interruption of the excitation the fluid, normally blood, flowing past the sensing element will cool it until the element reaches the temperature of the surrounding fluid. From this cooling of the sensing element data about the fluid flow rate are determined.

Thus in the present invention a separate heating element is not needed, but one and the same element is used for heating and sensing, and the above-mentioned cooling is measured by the sensor itself. The heating and sensing element can also be made with a very small thermal mass, and consequently a low thermal inertia, such that a quick sensor is obtained which makes it possible to sense temperature variations during single cardiac cycles. Also in situations with slow pressure variations in the fluid in question the temperature variation can be correctly followed in short time windows.

For a reliable function of the present invention a good thermal contact between sensing element and the flowing medium has to be maintained, i.e. intermediate layers like overgrowth and protein layers, must be avoided. The voltage source of the sensor according to the invention is therefore arranged to apply on said combined heating and sensing element a vibration exciting voltage which is adapted to clean the surface of said heating and sensing element from tissue overgrowth and adhering proteins. The above-mentioned vibration of the sensing element for heating purposes has thus appeared to also have an efficient cleaning effect on the surface of the sensing element. This cleaning action is a very important advantage of the invention.

According to an advantageous embodiment of the sensor according to the invention the flow determining means is adapted to determine the decay of the temperature of said combined heating and sensing element after interruption of the heating and to determine said data about the body fluid flow rate from said decay. Thus from the temperature decay curve after interruption of the heating important flow data are derived.

Brief Description of the Drawings

To describe the invention in greater detail embodiments of the invention, chosen as examples, will now be described with reference to the accompanying drawings, on which figure 1 is a schematic drawing of an electrode lead having a ring electrode suitable for use in the sensor according to the invention, and figures 2 and 3 illustrate qualitatively the temperature decay curves sensed by the sensing element from which flow rate data are determined in two different ways.

Detailed Description of Preferred Embodiments

Figure 1 shows an electrode lead 11 for a pacemaker with a tip electrode 200 and an indifferent ring electrode 100. The lead 11 also includes three conductors, one conductor 12 connected to the tip electrode 200 and two conductors 13, 14 connected to the ring electrode 100.

The ring electrode 100 is coated by piezoelectric material which is vibrated by application of an excitation voltage on this electrode. The piezoelectric material is then heated by the vibrations as explained above. After interruption of the excitation the cooling is determined from the pyroelectric signal obtained from the piezoelectric material. When the lead 11 is implanted in the circulatory system of a human being this cooling is depending on the flow of body fluid past the ring electrode 100. From the cooling, flow data of the fluid can consequently be derived.

Such a sensor can preferably be designed as a piezoelectric sensor, for instance of the kind described in WO 99/53972. From such a sensor not only a pyroelectric signal can be obtained but also e.g. pressure signals including several components from which different kinds of information can be filtered out.

Electric circuits for applying the AC excitation voltage on the piezoelectric sensing element and for measuring the pyroelectric signal from the sensing element are not further described here since it is well-known to the man skilled in the art how to design such circuits.

Figures 2 and 3 illustrate qualitatively the temperature variation as a function of time when practising the invention. At time t=0 the excitation voltage is applied to the sensing element which is heated as explained above. The temperature T then increases from T_0 which is the temperature of the body fluid in question, normally blood. When the temperature has been increased during a predetermined time period to a value T_7, e.g. 1°C, above the blood temperature T0, the excitation voltage is switched off, at time t_0, and the heating is stopped. If this predetermined time period does not result in a sufficient heating, the excitation heating is continued during a second predetermined time period. The blood flowing past the sensing element then cools the element and its temperature is decreasing until the temperature T_0 of the surrounding blood is reached again. The temperature decay curve starting at the time t_0 is an exponential curve generally described by an equation of the type

$$T = (T_7 - T_0)\ e^{-t/\tau}$$

where T denotes the temperature of the sensing element for $t \geq t_0$. τ is a constant determined by the thermal mass of the sensing element. The shape of the temperature decay curve after the time t_0 can thus be determined from the temperature T and the time t which are measurable quantities. Since the temperature decay in its turn depends on the flow rate of blood flowing past the sensing element and cooling it, data for this flow are thus derivable from the temperature decay curves.

Two different situations of cooling are shown in each of figures 2 and 3. Curve I illustrates a slower cooling than curve II which in its turn indicates that curve I represents a situation of a lower flow than curve II, provided that other conditions are similar.

With reference to figure 2, by measuring the temperature T at e.g. three predetermined times, t', t'', and t''' after interrupting the heating, at t_0, the decay of the curves can be determined Thus for the example represented by curve I the temperatures T_1, T_2, and T_4 are measured, and for the example represented by curve II the temperatures T_3, T_5, and T_6 respectively.

The temperature drop in the time interval $t'' - t'$ according to curve I is $T_1 - T_2$ and according to curve II $T_3 - T_5$. From the figure it directly appears that

$$T_1 - T_2 < T_3 - T_5$$

thus indicating that the cooling in the example represented by curve I is slower than the cooling in the example according to curve II, as mentioned above. Correspondingly, the temperature drop in the time interval $t''' - t''$ is slower for curve I than for curve II.

Figure 3 shows a corresponding diagram, illustrating an alternative way of determining the temperature decay, by measuring the times t_1, t_2, t_3, t_4, t_5 and t_6, at which three predetermined temperatures T', T'', and T''' are reached after interrupting the heating at t_0 for the two situations illustrated. Also from this figure it directly appears that the time for the temperature to drop from e.g. T' to T'' is longer in the situation according to curve I than according to curve II, viz.

$$t_5 - t_3 > t_2 - t_1$$

thus indicating that curve I is illustrating a situation of slower cooling than curve II.

CLAIMS

1. Implantable flow sensor intended to be implanted into the circulatory system of a human being for sensing the flow of a body fluid, comprising a heating element for heating a pyroelectric sensing element of a pyroelectric detector which is adapted to generate a temperature signal representing changes in temperature of its sensing element after interruption of the heating, and a flow determining means for determining from said temperature signal data about the body fluid flow rate from cooling of said sensing element after interruption of the heating, **characterized in** that said heating element and said sensing element are one and the same, combined heating and sensing element, in that said combined heating and sensing element is piezoelectric, and in that a voltage source is provided for applying a vibration exciting voltage on said combined heating and sensing element for heating the element.
2. Sensor according to claim 1, **characterized in** that said voltage source is arranged to apply on said combined heating and sensing element a vibration exciting voltage which is adapted to clean the surface of said heating and sensing element from tissue overgrowth and adhering proteins.
3. Sensor according to claims 1 or 2, **characterized in** that said flow determining means is adapted to determine the decay of the temperature of said combined heating and sensing element after interruption of the heating and to determine said data about the body fluid flow rate from said decay.
4. Method for measuring the flow of a body fluid in the circulatory system of a human being, wherein a pyroelectric sensing element, intended to be implanted into said circulatory system, is heated by a heating element, whereupon a pyroelectric signal from said sensing element is detected when the temperature changes after interrupted heating for determining the cooling of the sensing element, and data about the body fluid flow rate are determined from said cooling after interrupted heating, **characterized in** that said heating element and said sensing element are one and the same, combined heating and sensing element, in that said combined heating and sensing element is piezoelectric, and

in that said combined heating and sensing element is heated by application of a vibration exciting voltage on the element.

5. Method according to claim 4, **characterized in** that vibrations of said combined heating and sensing element are excited in order to clean the surface of the element from tissue overgrowth and adhering proteins.

6. Method according to claim 4 or 5, **characterized in** that the decay of the temperature of said combined heating and sensing element is determined after interrupting the heating.

7. Method according to claim 6, **characterized in** that the temperature of said combined heating and sensing element is measured at three predetermined times after interrupting the heating, and in that the decay of the temperature after interrupting the heating is determined from these measurements.

8. Method according to claim 7, **characterized in** that the times after interrupting the heating at which the temperature reaches three different predetermined temperature values are recorded, and in that the decay of the temperature after interrupting the heating is determined from these recordings.

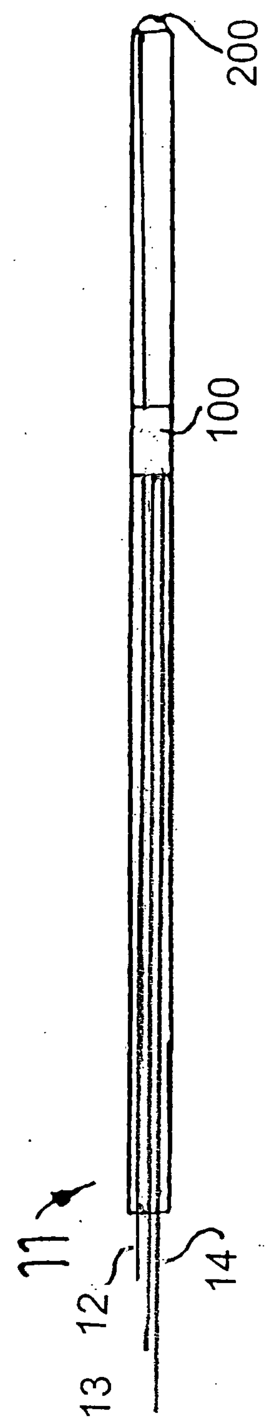

Figure 1

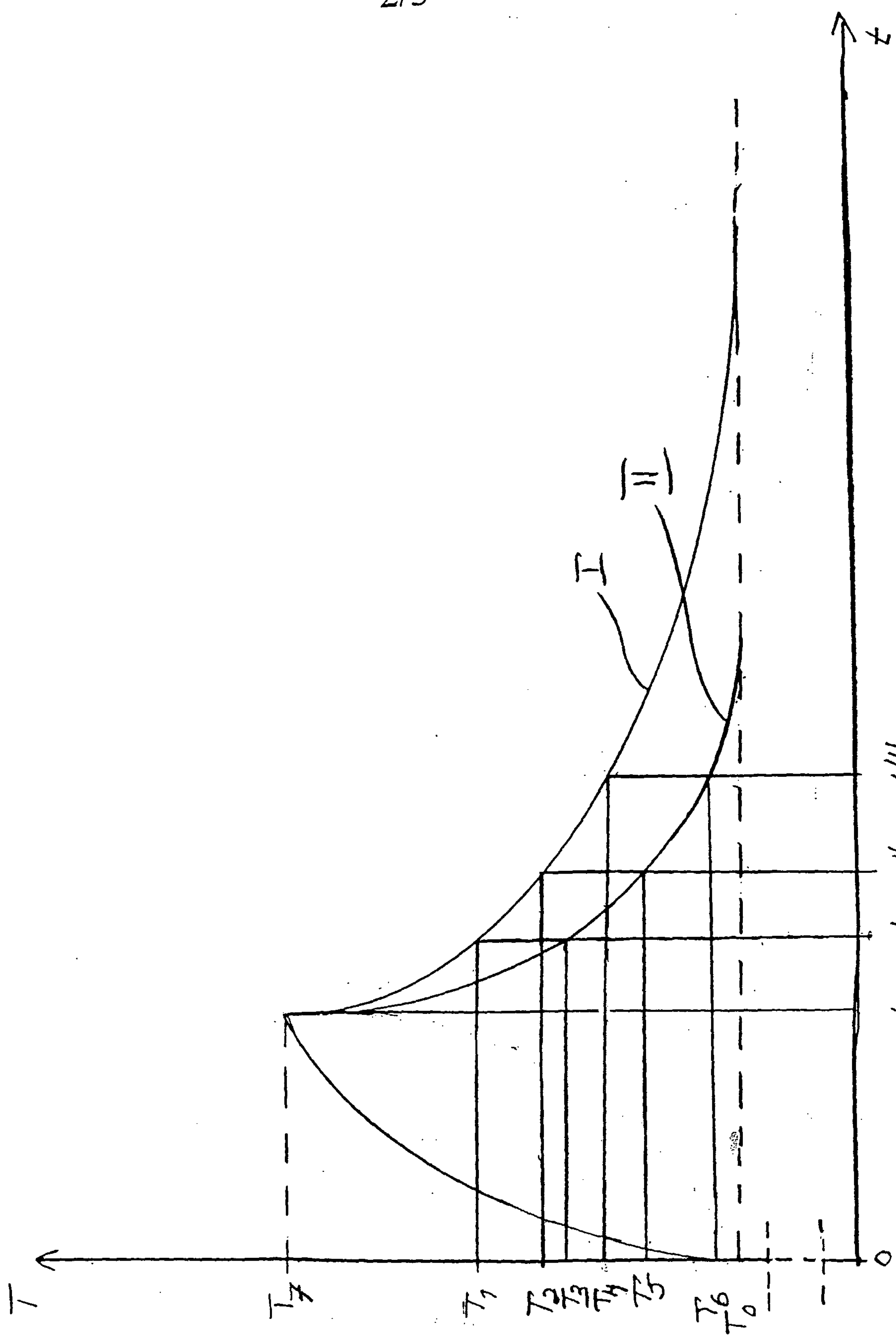

Figure 2

3/3

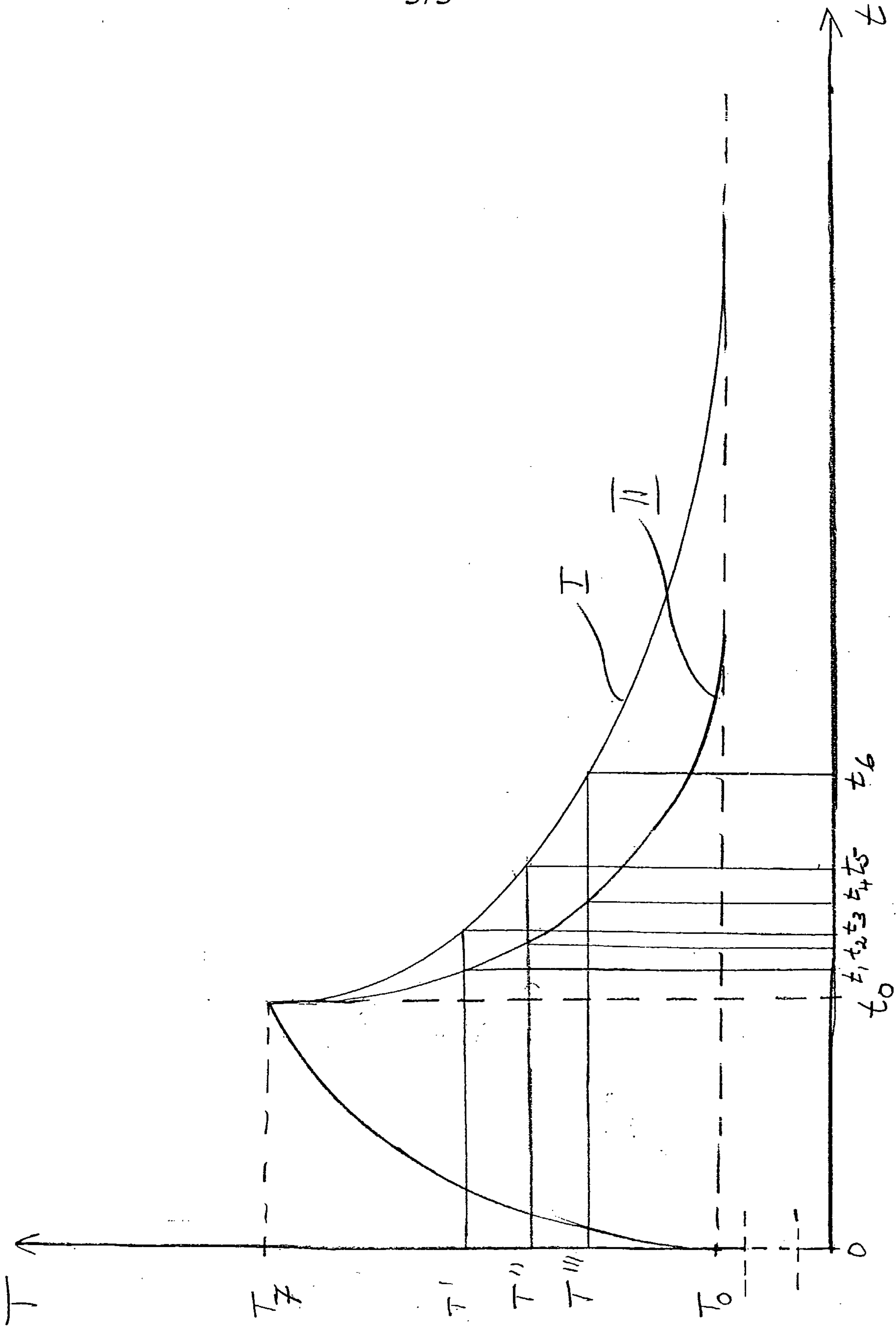

Figure 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000945

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B, G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5598847 A (HERMAN L. RENGER), 4 February 1997 (04.02.1997), abstract --	1-8
A	US 4770037 A (DOMINIQUE NOIR ET AL), 13 Sept 1988 (13.09.1988), abstract --	1-8
A	US 3798967 A (ANTONIUS CORNELIS MARIA GIELES ET AL), 26 March 1974 (26.03.1974), abstract --	1-8
A	US 20040007245 A1 (HANS HECHT ET AL), 15 January 2004 (15.01.2004), abstract --	1-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 2006	17-01-2006
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Lars Jakobsson/MN Telephone No. +46 8 782 25 00

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6524256 B2 (MAX SCHALDACH ET AL), 25 February 2003 (25.02.2003), abstract --	1-8
A	US 6571130 B1 (KARIN LJUNGSTRÖM ET AL), 27 May 2003 (27.05.2003), abstract -- --------	1-8

INTERNATIONAL PATENT CLASSIFICATION (IPC):

A61B 5/026 (2006.01)
G01F 1/688 (2006.01)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2005/000945

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 4-8
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 4-8 relates to a method of treatment of the human body by a diagnostic method practised on the human or animal body/Rule 39.1(iv). Nevertheless a search has been executed for these claims. The search has been based on the alleged effects of the device.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000945

US	5598847	A	04/02/1997	NONE			
US	4770037	A	13/09/1988	AT	51295	T	15/04/1990
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				US	6526984	B	04/03/2003
				WO	0005908	A	03/02/2000
				WO	9953972	A	28/10/1999
				WO	9954266	A	28/10/1999
				SE	513590	C	09/10/2000
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